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PTO/SB/21 (08-00)

# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/805,293
Filing Date	March 12, 2001
First Named Inventor	Halsted, Charles H.
Group Art Unit	1645
Examiner Name	
Attorney Docket Number	02307O111710

Total Number of Pages in This Submission

## ENCLOSURES (check all that apply)

☐ Fee Transmittal Form

☐ Fee Attached

☐ Amendment / Response

☐ After Final

☐ Affidavits/declaration(s)

☐ Extension of Time Request

☐ Express Abandonment Request

☒ Information Disclosure Statement

☐ Certified Copy of Priority Document(s)

☐ Response to Missing Parts/  
Incomplete Application

☐ Response to Missing  
Parts under 37 CFR  
1.52 or 1.53

☐ Assignment Papers  
(for an Application)

☐ Drawing(s)

☐ Licensing-related Papers

☐ Petition Routing Slip (PTO/SB/69)  
and Accompanying Petition

☐ Petition to Convert to a  
Provisional Application

☐ Power of Attorney, Revocation  
Change of Correspondence Address

☐ Terminal Disclaimer

☐ Request for Refund

☐ CD, Number of CD(s)

☐ After Allowance Communication to  
Group

☐ Appeal Communication to Board of  
Appeals and Interferences

☐ Appeal Communication to Group  
(Appeal Notice, Brief, Reply Brief)

☐ Proprietary Information

☐ Status Letter

☒ Other Enclosure(s)  
(please identify below):

Return Postcard; Form PTO-1449; PCT  
Search Report; copies of References cited  
therein

Remarks

The Commissioner is authorized to charge any additional fees to  
Deposit Account 20-1430.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm  
and  
Individual name

Townsend and Townsend and Crew LLP

Laurence J. Hyman

Reg No. 35,551

Signature

Date

## CERTIFICATE OF MAILING

Express Mail Label: EL104786497US

I hereby certify that this correspondence is being deposited with the United States Postal Service with "Express Mail Post Office to  
Address" service under 37 CFR 1.10 on this date Aug. 9, 2001 and is addressed to:

Assistant Commissioner for Patents, Washington, D.C. 20231

Typed or printed name

Patricia Andrews

Signature

Patricia Andrews

8/9/01 Date

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comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark  
Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for  
Patents, Washington, DC 20231.

SF 1255088 v1

EL104786497US

Mailed: August 9, 2001  
To: Assistant Commissioner for Patents  
Washington, D.C. 20231  
"Express Mail" Label No. EL104786497US  
TOWNSEND and TOWNSEND and CREW LLP

PATENT  
Attorney Docket No.: 023070-111710US  
Client Reference No.: 2000-254-1



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Charles H. Halsted et al.

Application No.: 09/805,293

Filed: March 12, 2001

For: MUTATIONS IN HUMAN  
GLUTAMATE CARBOXYPEPTIDASE  
II GENE IMPACTING FOLATE  
METABOLISM, AND DETECTION OF  
AFFECTED INDIVIDUALS

Examiner:

Art Unit: 1645

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. Also enclosed is a copy of the Search/Examination report to the corresponding PCT application. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

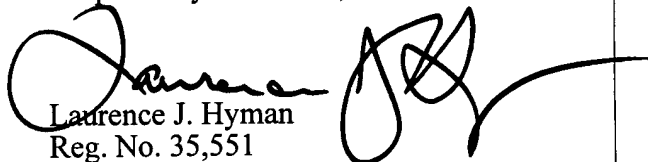
As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Application No.: 09/805,293

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Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

  
Laurence J. Hyman  
Reg. No. 35,551

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: 415-576-0200  
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LJH:pja

SF 1254125 v1



# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: LAURENCE J. HYMAN  
TOWNSEND AND TOWNSEND AND CREW LLP  
TWO EMBARCADERO CENTER, 8TH FLOOR  
SAN FRANCISCO, CA 94111-3834

## PCT

### NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Date of Mailing (day/month/year) 25 JUN 2001	
Applicant's or agent's file reference 23070-11171P	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US01/07880	International filing date (day/month/year) 16 APRIL 2001
Applicant THE REAGENTS OF THE UNIVERSITY OF CALIFORNIA	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.  
 Filing of amendments and statement under Article 19:  
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):  
 When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.  
 Where? Directly to the International Bureau of WIPO  
 34, chemin des Colombettes  
 1211 Geneva 20, Switzerland  
 Facsimile No.: (41-22) 740.14.35  
 For more detailed instructions, see the notes on the accompanying sheet.
2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
  - ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
  - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. Further action(s): The applicant is reminded of the following:
 

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LISA ARTHUR <i>Lisa Arthur</i> Telephone No. (703) 308-0196
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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 23070-11171P	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US01/07880	International filing date (day/month/year) 16 APRIL 2001	(Earliest) Priority Date (day/month/year) 13 MARCH 2000
Applicant THE REAGENTS OF THE UNIVERSITY OF CALIFORNIA		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:
  - ☐ contained in the international application in written form.
  - ☒ filed together with the international application in computer readable form.
  - ☐ furnished subsequently to this Authority in written form.
  - ☐ furnished subsequently to this Authority in computer readable form.
  - ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
  - ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
2. ☐ Certain claims were found unsearchable (See Box I).
3. ☐ Unity of invention is lacking (See Box II).
4. With regard to the title,
  - ☒ the text is approved as submitted by the applicant.
  - ☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,
  - ☒ the text is approved as submitted by the applicant.
  - ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is Figure No. \_\_\_\_
  - ☐ as suggested by the applicant.
  - ☐ because the applicant failed to suggest a figure.
  - ☐ because this figure better characterizes the invention.

☒ None of the figures.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/07880

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 01/68; G01N 33/53; C07H 21/04

US CL : 435/6, 7.4; 536/23.5

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6, 91.2; 7.47.9, 7.92; 536/23.5, 24.32, 24.33

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST, MEDLINE, EMBASE, BIOSIS, CAPLUS  
folate, glutamate carboxypeptidase, polymorphism

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	DEVLIN et al. Glutamate carboxypeptidase II: a polymorphism associated with lower levels of serum folate and hyperhomocysteinemia. Human Molecular Genetics. 22 November 2000, Vol. 9, No. 19, pages 2837-2844, see entire document.	1-30
A	HALSTEAD et al. Polypoly- $\gamma$ -glutamate carboxypeptidase from pig jejunum. Journal of Biological Chemistry. 07 August 1998, Vol. 273, No. 32, pages 20417-20424, see entire document.	1-30
A	TIFFANY et al. Characterization of the Enzymatic Activity of PSM: Comparison with Brain NAALADase. The Prostate. 01 April 1999, Vol. 39, No. 1, pages 28-35, see entire document.	1-30

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

04 JUNE 2001

Date of mailing of the international search report

25 JUN 2001

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer  
LISA/ARTHUR

Telephone No. (703) 308-0196

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty and of the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

**What parts of the international application may be amended ?**

The claims only.

The description and the drawings may only be amended during international preliminary examination under Chapter II.

**When ?** Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

**Where not to file the amendments ?**

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

**How ?** Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

**What documents must/may accompany the amendments ?**

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confounded with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.